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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/692,785	10/27/2003	Egisto Boschetti	9676-314-999	1038
20582	7590	06/02/2006	EXAMINER	
DUANE MORRIS LLP 380 LEXINGTON AVENUE NEW YORK, NY 10168			JONES, DAMERON LEVEST	
			ART UNIT	PAPER NUMBER

1618

DATE MAILED: 06/02/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/692,785

Applicant(s)

BOSCHETTI, EGISTO

Examiner

D. L. Jones

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 07 March 2005 and 16 March 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,4-11,15-30 and 56-62 is/are pending in the application.
- 4a) Of the above claim(s) 22-30 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,4-6,11,15-18 and 56 is/are rejected.
- 7) ☒ Claim(s) 7-10,19-21 and 57-62 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>3/7/05</u> . | 6) <input type="checkbox"/> Other: _____ |

ACKNOWLEDGMENTS

1. The Examiner acknowledges receipt of the amendment filed 3/16/06 wherein the specification was amended; claims 1, 6, 11, and 18 are amended; claims 2, 3, 12-14, and 31-55 are canceled; and claims 57-62 are added.

Note: Claims 1, 4-11, 15-30, and 56-62 are pending.

RESPONSE TO APPLICANT'S ARGUMENTS/AMENDMENT

2. The Applicant's arguments/amendment filed 3/16/06 to the rejection of the claims made by the Examiner under 35 USC 103 and/or 112 have been fully considered and deemed persuasive-in-part for the reasons set forth below.

112 Rejections

The 112 rejections are WITHDRAWN for reasons of record.

103 Rejections

I. The 103 rejection over Barnes et al is WITHDRAWN for reasons of record in Applicant's response.

II. The rejection of claims 1, 4-6, 11, 15-18, and 56 under 35 USC 103(a) as being unpatentable over Bachtsi et al (J. Microencapsulation, 1995, Vol. 12, No. 1, pp. 23-35) is MAINTAINED for reasons of record in the office action mailed 11/16/05 and those set forth below.

Applicant asserts that it would not have been obvious to modify the microspheres of Bachtsi to produce microspheres useful for embolization wherein said microspheres comprise the components set forth in the independent claims and are sterile.

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Applicant's arguments are non-persuasive for the following reasons. First, Applicant is reminded that the intended use of the microsphere does not impart patentability to microsphere. A statement of intended use carries patentable weight in a method claim. Secondly, in regards to Applicant's assertions that while the reference mentions the controlled delivery of various biomolecules, since it is mentioned in the background, it is a mere obvious to try approach. An 'obvious to try' standard is deemed permissible when there is a suggestion or teaching that the claimed form of the prior art compound could or should be prepared. In this particular instant, the prior art discloses that hydrogels are used as controlled deliver devices for various biomolecules including drugs, enzymes, and antibodies and that incorporation and/or delivery of the bioactive material may be accomplished by the swelling/deswelling of the hydrogel. Furthermore, it is common in the art to administer hydrogels to a subject that upon reaching a desired target area, the stimuli responsive hydrogel sell or deswell in response to changes such as pH, temperature, ionic strength, mechanical stresses, and/or other environmental stimuli. Thus, a skilled practitioner in the art would be motivated to use a sterile composition for administration purposes because, for example, if a hydrogel is delivering an enzyme, antibody, drug, etc. to a desired location, if the composition it not sterile, then the effects of the composition would not be confusing since one would not know whether the effects are due to impurities of the non-sterile composition or the actual hydrogel composition administered. Hence, since the introduction of Bachtsi et al discloses information on hydrogels and possible stimuli

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and their use as delivery devices for biomolecules, the reference provides motivation to use a sterile composition.

WITHDRAWN CLAIMS

3. Claims 22-30 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention/species.

CLAIM OBJECTIONS

4. Claims 7-10, 19-21, and 57-62 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Note: The claims are distinguished over the instant invention because the limitations of the dependent claims in combination with their respective intervening independent claim is distinct over the prior art of record.

5. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any


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extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to D. L. Jones whose telephone number is (571) 272-0617. The examiner can normally be reached on Mon.-Fri., 6:45 a.m. - 3:15 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Hartley can be reached on (571) 272-0616. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



D. L. Jones
Primary Examiner
Art Unit 1618

May 30, 2006